

Structured Product Labeling (SPL) OTC Sub-team Teleconference
August 24, 2009, 1:00 – 2:00 pm ET
Call Summary

I. Call Attendees (based on emails received)

Attendance is based on email replies received. Call participants who are not listed below but were on the call (or you are listed and were not on the call) should notify Marcia Howard.

- ✚ Paule Belony, The Belony Group LLC
- ✚ David Brown, Colgate Palmolive Company
- ✚ Pete Carlson, EcoLab
- ✚ Maureen Kapustynski, Cadbury
- ✚ Mike Koenig (FDA)
- ✚ Juris Lazdins, Novartis Consumer Health, Inc.
- ✚ Devon Morgan, Perrigo Company (sub-team co-leader)
- ✚ Jeff Poisson, i4i
- ✚ Janet Riffitts, McNeil Consumer Healthcare
- ✚ Gary Saner, Reed Technology & Information Services, Inc.
- ✚ Dave Schilling, Chattem, Inc.
- ✚ Howard Shatz, Data Conversion Laboratory, Inc.
- ✚ Siobhan Stevens-Miles, Merck & Co., Inc.
- ✚ Cynthia Thompson, Kimberly-Clark Corporation
- ✚ Karen Vescovi, Church & Dwight Co., Inc.
- ✚ Elise Wolf, Combe Incorporated
- ✚ Barbara Wolfe, Wyeth Consumer Healthcare
- ✚ Reena Zade, Dr. Reddy's Laboratories, Inc.
- ✚ Florence Change, National Library of Medicine (NLM; guest)
- ✚ Brent Bolan, NLM (guest)
- ✚ David Hale, NLM (guest)
- ✚ Marcia Howard, CHPA staff (sub-team liaison)

II. Next Standing Teleconference: September 21, 2009 (September 7th call **CANCELLED** due to Labor Day holiday; **NOTE:** The FDA Monday webinar & QA&A training sessions will also be cancelled for the holiday)

III. Discussion Topics

- A. NLM Pillbox Initiative
Florence Chang, Brent Bolan, and David Hale, all of the National Library of Medicine (NLM) were guests on today's call. They addressed the questions and concerns previously outlined by the sub-team.
- Confirm companies will submit the actual product samples to be photographed directly to NLM.
Response: NLM and FDA Center for Drug Evaluation & Research (CDER) are working to develop the process. The process will most likely include having

companies send the samples to an FDA facility; the samples would be received by a pharmacist and samples destroyed at a site on Ft. Detrick (Frederick, MD); a paper trail for destruction would exist.

- Outline general steps, responsibilities, and timing for the imaging process.
Response: NLM would obtain the samples from FDA, photograph the medicine and destroy the sample. The images would be sent to the sponsor.
- What is the source of the photos, i.e., who provides the images?
Response: NLM provides the images to the sponsors. Sponsors would receive a master file with the images.
- Who will be responsible for posting the images, and how would updates and changes be processed?
Response: Interested in getting industry input on this issue. The hope is that the data would be archived.
- If NLM produces the photos, what chain of custody and processes are/need to be in place to ensure accuracy of medication photographed (i.e., how will NLM ensure that the accuracy of the sample is what is captured?)
Response: NLM is currently working with CDER to establish processes, but will consider issues such as the minimum amount of info that would be needed for the program, safety of the photographers, DEA status, and robust quality control. The final approval rests with the individual sponsor.
- What internal corporate resources, if any, will be needed to participate in the initiative?
Response: Initially NLM will provide the majority of the resources needed but companies will have the expense of packaging (e.g., padded shipping material, not a medicine bottle), shipping, and handling for the sample. The long term goal is to have sponsors assume the process once an open standard is developed. The sponsor would then simply transmit the image to NLM.
- Will the Pillbox initiative replace the Physician's Desk Reference (PDR) or will there be two sources of information?
Response: The PDR is privately owned and this initiative will not compete with this publication. NLM is simply the data repository and has no intention of interfering with private enterprise.
- As some companies also post images on their own websites, what is the potential impact, if any, on having the images posted at corporate websites as well as the NLM website?
Response: The images could be posted both places.

- Would it be possible to link the image with SPL submissions?
Response: Yes, the goal is to work towards linking the image and label information in SPL.
- Will both sides of the product be photographed even if imprints are only featured on one side of the solid oral dosage form?
Response: Both sides of the sample will be photographed. A composite image of the obverse and reverse will be created.
- What happens if the shape of the tablet is copyrighted or trademarked?
Response: The trademark will be displayed visibly as part of the image. The sample will be reproduced in whole form without alteration so no infringement on trademark or copyright issues is anticipated.
- Other discussion points
 - The images will be taken in the visible spectrum only so there is minimal/no concern about counterfeiting, especially for “low level” operations.
 - The SPL image submission can be independent of the having images posted to the Pillbox website. If a company does not want the image posted to the Pillbox site, a request can be sent to NLM asking that the image not be made available.
 - At this time, there are no direct costs to companies but there will be indirect costs, such as packing, shipping costs, and staff to process. Currently CDER and NLM are covering all other costs.
 - Sponsors will receive an SPL-formatted image and the raw image (separate files). The SPL image will be a jpeg file to comply with existing specs (approximately 60 kb). The master image will be approximately 22MB.
 - The sponsor has final approval of the final files, one for SPL submissions and one for Pillbox. Only the sponsor can submit images with the SPL file. Images not associated with the SPL submission will have an appropriate disclaimer.
 - The Pillbox initiative and posting to the NLM site is a completely voluntary process and has no bearing on SPL submissions and is not part of any regulation or statute.
 - NLM would like feedback from industry about how to manage process for re-submissions.
 - The hope is that one day, medicines can be identified by a machine-based program based on photos accessible from a mobile or portable device (e.g., use PDA to identify the medicine in question).
 - OTCs can be included in the pilot program if industry wishes to participate. Inclusion of OTCs would be beneficial in the development process.

- NLM is interested in dialogue, including discussion about key components of the program.
- NLM has a β -test program for Pillbox currently available for review. Please contact David Hale (david.hale@nih.gov) for log-in information.
- David is willing to participate on future sub-team calls, as appropriate, but is also willing to speak with individual companies about the initiative.

B. Posting OTC information to DailyMed/FDA Facts page

Only seven responses were received for the short survey (yes/no/yes with caveats) about whether or not monograph OTC product listing info should be posted to the DailyMed/FDA Facts (currently a prototype) website. It was agreed that the survey would be reopened until September 1, 2009, to collect additional responses. It will be assumed that sub-team members who do not respond by the deadline are not interested in doing so. Currently, ANDA and NDA OTC products are posted but not monograph OTCs. The FDA is discussing this issue and has asked industry for its feedback.

Survey Link: Please respond by 5:00 pm ET on September 1, 2009

http://www.surveymonkey.com/s.aspx?sm=oBMxXYjgWxB5FnKRzMJ5qQ_3d_3d

Companies are encouraged to provide their own feedback to FDA regardless of the decision of the sub-team. Although no timeframe was given, comments should be sent to the agency as soon as possible.

IV. Open Discussion by Sub-team Members

Due to time constraints, there was no open discussion. Sub-team members were asked to email questions and/or concerns to Paula Markert (GlaxoSmithKline), Devon Morgan, and/or Marcia Howard. Issues can also be brought forward for discussion on the September 24, 2009, teleconference.

V. FDA Data Council Information (*not all-inclusive*) – **NOTE: New Info Included**

- A. The FDA Data Standards Council's website was updated Tuesday, August 25, 2009, to include updated terminology:
UNII update -
<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucml62523.htm>

- B. Updated terminology XML Files (include updated UNII XML file) -
<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucml69455.htm>
- C. The FDA Data Standards Council's website was updated Tuesday, August 18, 2009, to include updated terminology:
 - 1. UNII update -
<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucml62523.htm>
 - 2. Updated terminology XML Files (include updated UNII XML file) -
<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucml69455.htm>
- D. The FDA Data Standards Council's website was updated Friday, August 14, 2009, to include updated terminology:
 - 1. UNII update -
<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucml62523.htm>
 - 2. Updated terminology XML Files (include updated UNII XML file) & additional validation (Postal Code Validation file) -
<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucml69455.htm>

VI. Upcoming SPL Educational Forums/Information

- A. FDA SPL R4 Training Sessions – Please visit website for updated information regarding training courses.
<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucml55705.htm>

- 1. **FDA Training Sessions:** Monday webinars at 10:00 am ET and Q&A sessions at 11:30 am ET (same for both; cancelled for Federal holidays)

UPDATED Telephone number: 1-866-775-9435

UPDATED Participant pass code: 5753366

Please dial-in early as there are a limited number of ports and when they are exhausted, no one else will be able to connect to the conferences.

NOTE 1: Sub-team members are asked to send OTC-specific questions, issues, and concerns to Marcia no later than September 14, 2009. Lonnie Smith (FDA) has requested feedback so that he can tailor future OTC SPL R4

training sessions to cover these topics. A consolidated list will be circulated for discussion on the September 24th call prior to send to FDA.

NOTE 2: It is highly recommended that you sign up to receive automatic updates from the Data Standard Council website so you will get announcements about training opportunities, UNII updates, etc. as soon as they are released. This will minimize possible delays in receiving the info should Marcia Howard be unable to forward the message immediately.

2. **SPL Process Communication Forum (Process Team):** Alternating Wednesdays 1:00 - 2:30 pm ET (unless cancelled; opposite to ERDL calls)
Telephone number: 877-423-2663
PIN#: 558089
Please email Process Team co-leaders Terry Brunone (Theresa.M.Brunone@gsk.com) or Mary Beth Wilusz (mary_beth_wilusz@merck.com) if you want to get the email information.
3. **SPL ERDL Sub-team calls:** Alternating Wednesdays at 1:00 pm ET (unless cancelled)
Telephone number: 866-217-3840
Conference Code: 4286445422
Please email sub-team leader Michael Fahmy if you want to get the email information (michael.fahmy@bms.com).
4. **SPL Generics Sub-team calls:** First Tuesdays of each month at 1:00 pm ET (unless cancelled)
Telephone number: 866-618-6746 (toll-free)
201-527-2133 (international/caller paid)
Access Code: 8957842
Please email sub-team leader Virginia Hogan if you want to get the email information (Virginia.Hogan@tevausa.com).

MDH/08-26-09

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